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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/482,785 06/07/95 ADAMS

C

30429-39US02

EXAMINER

WALSH, S

ART UNIT

PAPER NUMBER

7

18M1/1228

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1812

DATE MAILED:
12/28/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 1 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☒ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1-9, 11, 12, 18, 26, 47-50 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1, 2, 4, 6, 7, 8, 11, 18, ²⁶ and 47-50 are rejected.

5. ☒ Claims 3, 5, 9, 12 are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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EXAMINER'S ACTION

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Part III DETAILED ACTION

1. The preliminary amendments have been entered.

2. The following allowable claim is suggested for the purpose of an interference:

5 An isolated polynucleotide consisting of a nucleotide sequence encoding the amino acid sequence indicated in Figure 4, SEQ ID NO:9.

The suggested claims must be copied exactly, although other claims may be proposed under 37 C.F.R. § 1.605(a).

10 APPLICANT SHOULD MAKE THE SUGGESTED CLAIM WITHIN ONE MONTH FROM THE DATE OF THIS LETTER. FAILURE TO DO SO WILL BE CONSIDERED A DISCLAIMER OF THE SUBJECT MATTER OF THIS CLAIM UNDER THE PROVISIONS OF 37 C.F.R. § 1.605(a). THE EXTENSION OF TIME PROVISIONS OF 37 C.F.R. § 1.136(a) DO NOT APPLY TO THIS TIME PERIOD.

15 Claims 1-9, 11, 12 and 26 are considered unpatentable over the above suggested claim.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title fails to refer to the purified DNA claimed.

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4. The drawings are objected to for the reasons on the attached Form 948. Correction is required.

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Applicants' attention is directed to the reminder on the reverse side of the Form 948. The Brief Description of the Drawings will require amendment by Applicants to refer to the subfigures for Figs 3, 5 and 10.

5 5. This application discloses and claims only subject matter disclosed in prior application Serial No. 08/082,845 filed 6/23/93, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. § 120 and 37 C.F.R. § 1.78.

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6. The disclosure is objected to because of the following informalities: Table 2 at page 53 is blank, see attached copy. It is noted that page 52, lines 26-27, refers to Figure 8 as a graph of the data in Table 2, but Applicants are reminded of the prohibition of new matter. Appropriate correction is required.

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7. This application fails to comply with 37 CFR 1.821(d) which requires the recitation of a SEQ ID NO: at each and every reference to a listed sequence. Claims 1 and 3 refer to a sequence displayed in a Figure without reciting the SEQ ID NO:. Correction is required.

20 8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it

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is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure. Applicants claim DNA encoding a functional equivalent of *S. pyogenes* DNase B enzyme, but the specification fails to disclose this DNA. The ordinary meaning of functional equivalent would be that an enzyme has the same or similar activity. There are many enzymes with the same or similar activity. See pp. 339-340 of Enzyme Nomenclature, copy enclosed. The specification fails to disclose how to make and/or use DNA encoding any of these functional equivalents. Accordingly, the claims are not commensurate with the disclosure.

Applicants claim a vector wherein DNA is linked to "at least one sequence from bacteriophage λ ". The specification fails to provide support for the scope of sequences claimed because anything from a dinucleotide up is literally embraced, but such sequences would not achieve any useful purpose. Only certain sequences from a bacteriophage could be used. Claims 6 and 7 should be revised to indicate sequences as supported by the disclosure.

Applicants claim a transcriptional fusion comprising "at least a portion" of the DNase B DNA sequence of claim 3. The claim literally embraces a single nucleotide fused to another gene. The specification fails to teach how to use such fusions.

Applicants claim a method using a promoter "originally associated with" the DNase B gene. Since the microorganism has only one chromosome, all promoters in the entire chromosome are associated in some degree with the gene. The specification fails to

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identify a specific promoter, and fails to teach how to make and/or use the promoter. The limitation that the promoter be homologous to all other bacterial promoters does not identify the promoter because homologous is a qualitative term, and all promoters are homologous by definition.

5 Claims 1, 2, 4, 6, 7, 8, 11, 18 and 47-50 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

9. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

10 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.
15 Patentability shall not be negated by the manner in which the invention was made.

 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the
20 time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were
25 made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

30 Claim 26 is rejected under 35 U.S.C. § 103 as being unpatentable over Yutsudo et al(T) in view of Lathe(R'). Applicant claims the genus of probes hybridizing with any DNA

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sequence coding for the amino terminal 23 amino acids of *S.p.* DNase B. Assuming an average degeneracy of 3 codons for each amino acid, there are 3^{23} (or about 9×10^{10}) different DNA coding sequences for the 23 amino acids, and the same number of perfectly complementary probes. When the probe genus is permitted 30% mismatch, the number of probes claimed is 30% greater. Yutsudo et al. disclose the first 21 amino acids of mitogenic factor (MF) from *S.p.*, page 33, Table II. The sequence disclosed by Yutsudo et al. is identical to residues 2-22 of Applicants' N-terminal amino acid sequence. Yutsudo et al. do not teach a probe. Lathe teaches probes deduced from amino acid sequence data, see entire document. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make Lathe's probe hybridizing with one of the DNA sequences encoding Yutsudo et al.'s 21 amino acid sequence. The genus of probes that would be prepared based on Yutsudo et al.'s sequence would overlap about 90% of Applicants' claimed genus.

10. SEQ ID NO:s 8 and 9 are free of the prior art of record.

Claims 3, 5, 9 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1, 2, 4, 6, 7, 8, 11, 18 and 47-50 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Walsh whose telephone number is (703)

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308-2957. The Examiner can normally be reached on Monday-Friday from 8:00AM to 4:00PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Garnette D. Draper, can be reached on (703) 308-4232.

5 Papers related to this application may be submitted to Group 1800 in Crystal Mall 1 by facsimile transmission, in conformity with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The FAX phone number for Art Unit 1812 is (703) 308-0294.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15 
Stephen Walsh, Ph.D.
Primary Examiner
Group 1800

20
SW
December 22, 1995

25
attachment: copy of specification page 53

TABLE 2

EQUIVALENCE OF RECOMBINANT DNase B WITH ISOLATED DNase B
IN DETERMINATION OF ANTI-DNase B ANTIBODY TITER